

PRODUCT SPECIFICATION

Product PN 10498303 (125 pk) & 10498304 (500 pk)

Mod. 984

Description NEUTRALIZING BUFFER SWABS

Rev. 02

Neutralizing Buffer Swabs



PRODUCT DESCRIPTION	<p>SWAB NEUTRAL BUF 4ml 125/PK (10498303) and 500/PK (10498304)</p> <p>Neutralizing buffer inactivates the bactericidal and bacteriostatic effects of chlorine and quaternary ammonium detergents. However, neutralizing buffer exhibits no toxic effects on microorganisms. This permits the transfer of swabbed organisms to the laboratory without loss in viability. Neutralizing buffer is not designed to culture and enumerate microorganisms.</p>
MANUFACTURER NAME	<p>GVS North America 63 Community Drive Sanford, Me 04073 Phone: +1.866.736.1250 eMail: CustomerCareGVSL@gvs.com - Website: www.gvs.com</p>
INTENDED USE / APPLICATION	<p>Neutralizing buffer swabs are used in the monitoring of surfaces for total bacterial count.</p>
MATERIALS	<p>Media: Neutralizing Buffer</p> <p>Color: Clear liquid</p> <p>Tube: clear polypropylene Screw Cap: Yellow polyethylene with silicone washer Swab: white cotton</p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Biocompatibility according ISO 10993-1 <input type="checkbox"/> IMDS <input checked="" type="checkbox"/> RoHS, directive 2002/95/CE <input type="checkbox"/> BSE/TSE, directive 2003/32/ <input type="checkbox"/> DEHP plasticizer Free and latex free <input type="checkbox"/> Aging <input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation) <input type="checkbox"/> Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) <input checked="" type="checkbox"/> Conflict minerals

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PRODUCT CHARACTERISTIC	<p>Clear buffer dispensed in self standing, round bottomed capped plastic vials. The cotton swab is secured inside the screw cap</p> <p>Physical: Vial: 12 x 84 mm Cap: 14 x 13.25 mm polyethylene with silicone washer Swab: 78mm long</p> <p>Dimensions: Volume/tube: 3.5 – 4.2 ml Incubation Temperature Range: 35°C ± 2°C Storage temperature Range: From 2°C to 8°C</p> <p>Biological: Product is sold sterilized. Toxicity: See SDS for further information.</p>
INSTRUCTIONS WARNINGS	<p>Product is temperature sensitive. Store at recommended temperature.</p>
PRODUCT SHELF LIFE	<p>12 months when stored properly</p>
STERILIZATION	<p>Product is sold sterilized.</p>
PACKAGING AND LABELLING	<ol style="list-style-type: none"> Vials are placed in box containing an insert. PN 10498303 contains 125 vials. PN 10498304 contains 500 vials. Box is labeled and shrink-wrapped. <p>LABEL:</p> 

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CERTIFICATE OF COMPLIANCE	With each shipment, GVS NA will provide the CoC with item number, lot number and expiration date. The Quality management system is in compliance with ISO 9001.																																						
VISUAL REQUIREMENTS	<p>Visual acceptance requirements apply when inspected under below conditions: Magnification: none Light type: normal room lighting</p> <table><tr><th colspan="3">Acceptance Requirement</th><th>Sampling Plan</th></tr><tr><td>1</td><td>Color – Clear liquid</td><td>all</td><td rowspan="2">100%</td></tr><tr><td>2</td><td>Vial appearance – no misshapen or leaking vials. Each vial contains a swab</td><td>none</td></tr></table>			Acceptance Requirement			Sampling Plan	1	Color – Clear liquid	all	100%	2	Vial appearance – no misshapen or leaking vials. Each vial contains a swab	none																									
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This material specification describes the properties of product above indicated. This document contains general requirements, material description, drawing references, defect specification, biological material requirements.																																							

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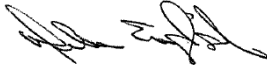
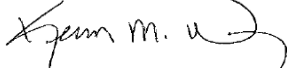
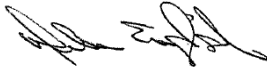
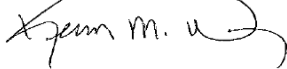
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REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
11/7/18	0	Initial release	Debra English/Manager Biochemistry Applications 	Kevin Wrigley/Director, Quality 
11/21/19	1	Corrected part number in Product Description section	Debra English/Manager Biochemistry Applications 	Kevin Wrigley/Director, Quality 

Customer Approval:

We accept this material specification as a part of the agreed terms of delivery

Company name _____

Approved by: _____
(Name, Function) (Signature)

Date _____
(Company stamp)

Please send back this document signed for approval. If we will not receive this specification signed, we consider the first order placed as implicit approval.